



serving statements that are completely unnecessary to the admission or denial of the requests. Defendants do not state specifically what part of the request is true as required by Rule 36. Instead, they interpose a qualified response, adding their own facts which are materially different from those requested to be admitted. Several responses lodge objections to requests but then purport to respond subject to the objections, which is inappropriate. Finally, Defendants assert several objections to various phrases used in the requests even though the context in which the phrases are used is clear and their meaning is well known to the Defendants. For these reasons, Plaintiffs request that the Court find Defendants' responses insufficient and deem the requests admitted or, in the alternative, order that they provide amended responses which conform to the spirit and intent of Rule 36, which is to eliminate from the case all issues that can be resolved prior to trial.

## II. ARGUMENT

Requests for admission are intended to “narrow the array of issues before the court, and thus expedite both the discovery process and the resolution of the litigation.” *Adventis, Inc. v. Consol. Property Holdings, Inc.*, 124 Fed. Appx. 169, 172 (4th Cir. 2005). Rule 36 specifically provides that if a request is not admitted the answer “must specifically deny it or state in detail why the answering party cannot truthfully admit or deny it. A denial must fairly respond to the substance of the matter; and when good faith requires that a party qualify an answer or deny only a part of a matter, the answer must specify the part admitted and qualify or deny the rest.” Fed. R. Civ. P. 36(4). “Generally, qualification is permitted if the statement, although containing some truth, standing alone out of context of the whole truth conveys unwarranted and unfair inferences.” *Diederich v. Department of Army*, 132 F.R.D. 614, 619 (S.D.N.Y. 1990) (internal quotation and alterations omitted). However, qualified answers should be the exception and not

the rule. *See* 8B CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE & PROCEDURE § 2260 (3d ed. 2010) ("It is expected that denials will be forthright, specific, and unconditional."). More importantly, "[a]ny qualifications should provide clarity and lucidity to the genuineness of the issue and not obfuscate, frustrate, or compound the references." *Wiwa v. Royal Dutch Petroleum Co.*, 2009 U.S. Dist. LEXIS 45621, at 17 (S.D.N.Y. May 21, 2009) (internal quotations omitted). Thus, answers that appear to be non-specific, evasive, ambiguous, and appear to go to the accuracy of the requested admissions rather than the "essential truth" contained therein are impermissible and must be amended. *Havenfield Corp. v. H & R Block, Inc.*, 67 F.R.D. 93, 97 (W.D. Mo. 1973). Courts "should not allow the responding party to make hair-splitting distinctions that frustrate the purpose of the Request." *United States v. Lorenzo*, 1990 U.S. Dist. LEXIS 7362, at 3 (E.D. Pa. June 14, 1990).

Where a party has answered or objected to a request for admission, Rule 36 allows the requesting party to seek a judicial determination of the sufficiency of the answer or objection. Fed. R. Civ. P. 36(6). The Court may reject unjustified objections and answers, and determine that, as to answers deemed non-compliant, either the matter be deemed admitted or an amended answer be served. *Id.*

**A. Defendants' self-serving responses do not "fairly respond to the substance of the matter" or meet the requirements for a "good faith" qualification**

The responses to requests to admit nos. 1, 2, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 107, 108, 109, 110, 111, 113, 114, 115, 116, 117, 120, 121, 122, 125, 126, 127, 128, 129, 130, 131, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 155, 156, 157, 158, 159, 162, 163, 164, 180, 181, 182, 184, 185, 186, 188, 217 fail to comply with Rule 36, which requires that "[a] denial must fairly

respond to the substance of the matter; and when good faith requires that a party qualify an answer or deny only a part of the matter, the answer must specify the part admitted and qualify or deny the rest.” *Id.* at 36(4) (emphasis added).

First, good faith does not require a qualified response to these requests. These requests constitute simple and straightforward questions, which could have been answered with equally straightforward and unqualified admissions or denials. Consider request no. 1, for example, which states:

**REQUEST NO. 1:** Admit that you never completed a controlled study involving live women with the actual TVT device (not a prototype) prior to marketing and selling the TVT in the U.S.

**RESPONSE:** Except as hereinafter expressly admitted, Defendants deny Request No. 1. Defendants admit that they did not complete a randomized controlled trial with the actual TVT device prior to marketing and selling the TVT in the United States, but Ethicon complied with FDA regulations and the 510(k) clearance process.

The self-serving statements regarding compliance with FDA regulations and the 510(k) clearance process are unnecessary. This extraneous information was not asked to be admitted, and there is nothing so complex, imprecise, unwarranted or unfair about the request that necessitates a qualified response. *See Havenfield*, 67 F.R.D. at 97 (finding that requests for admissions were not so complex or imprecise as to warrant qualified responses). If the Defendants completed a controlled study involving live women with the TVT device, they should say so. If not, they should say they did not.

Also illustrative is the response to request no. 108, which provides:

**REQUEST NO. 108:** Admit that the IFU has never stated to physicians that the TVT mesh can become deformed with tension during placement.

**RESPONSE:** Except as hereinafter expressly admitted, Defendants deny Request No. 108. Defendants admit that the actual words “TVT mesh can become deformed with tension during placement” are not stated in the IFU. Ethicon selected an appropriate mesh, and provided specific procedural steps for implantation in the IFU to prevent clinically significant deformation

that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant deformation.

Nowhere in request no. 108 are Defendants asked to admit whether they selected an “appropriate mesh,” whether they provided specific procedures in the IFU to prevent clinically significant deformation, or whether the TVT employs sheaths to prevent clinically significant deformation. Thus, once again, Defendants go out of their way to qualify their response with unsolicited, self-serving information. Defendants should not be allowed to subvert the purpose of Rule 36 simply because they may not like the potential implication of a straightforward admission. *See Cohane v. NCAA*, 2012 U.S. Dist. LEXIS 41217, at 5 (W.D.N.Y. Mar. 26, 2012) (finding qualification unnecessary, noting a party “should not be allowed to avoid admissions as to the process which was provided to him because of his argument that this process was insufficient or otherwise deficient.”). Defendants will have the opportunity to add context for its admissions at trial. Qualifications, however, are intended to provide clarity to the genuineness of the issue and not obfuscate or frustrate the references. There is no clarity provided by incorporating self-serving, non-responsive information. *See, e.g., Bullock v. Kraft Foods, Inc.*, 2011 U.S. Dist. LEXIS 123885, at 7-8 (E.D. Va. Oct. 26, 2011) (finding that responses violate Rule 36 because they include “nonresponsive and extraneous information . . . that do not ‘fairly respond to the substance of the matter.’”); *Havenfield*, 67 F.R.D. at 97 (finding that requests for admissions were not so complex or imprecise as to warrant qualified responses); *Wiwa*, 2009 U.S. Dist. LEXIS 45621, at 23 (finding vague and open-ended qualifications do not “provide clarity and lucidity to the genuineness of the issue,” but “obfuscate, frustrate or compound the references.”). Because Defendants’ responses do not “fairly respond to the substance of the matter” as required by Rule 36, they should be deemed insufficient.

Defendants' responses to request no. 105 and 106 also lack merit. In general, request no. 105 simply asks Defendants to admit that they knew by the end of 2007 that an article published in the International Urogynecology Journal reported that one problem with using the TVT is that the mesh easily deforms when tensioning under the urethra. But the Defendants never plainly admit or deny that they "knew" the referenced journal reported this event. Instead, Defendants use semantics to skirt the issue. Specifically, Defendants deny the request, except as otherwise admitted, and proceed to admit only that the journal had published the article, that the article was publicly available, and that the article included the language referenced in the request to admit. The response then goes on to quote additional passages from the referenced article under the auspices of putting the request to admit "in context." This type of response lacks merit. As held in *Starks-Harris v. Taylor*:

If the request for admission quotes a document and asks the other party to admit that the document contains the material quoted, it should be admitted if the quotation is accurate and denied if it is not. . . . If, on the other hand, the request for admission paraphrases a document, the request should be admitted if the paraphrase is accurate and denied if it is not.

*Starks-Harris v. Taylor*, 2009 U.S. Dist. LEXIS 16768 (N.D. Ind. Mar. 3, 2009) (internal quotations and citations omitted). There is nothing complicated or confusing about such a protocol—the Defendants just refuse to follow it.

Similarly, Defendants' responses to requests to admit nos. 1, 12, 19, 20, 28, 30, 31, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 85, 86, 88, 89, 90, 94, 95, 96, 97, 98, 99, 100, 101, 102, 107, 109, 110, 111, 112, 113, 114, 115, 116, 117, 127, 128, 129, 130, 131, 134, 135, 136, 140, 141, 142, 143, 145, 146, 147, 148, 149, 153, 156, 158, 159, 167, 168, 172, 175, 176, 179, 184 and 217 do not "fairly respond to the substance of the matter" because the admissions are materially different from what is requested and/or the admissions contain

unsolicited, extraneous facts. For instance, in request to admit no. 1, Defendants' qualified answer inexplicably and without explanation changes the specific terminology used in the request from "controlled study" to "randomized controlled trial," and completely omits the reference to "live women." Yet Defendants do not object that these terms are vague or ambiguous, nor do they offer alternative definitions for these terms. Qualified responses that "skirt the request" by admitting something different than required do not "fairly respond to the substance of the matter." *See Lorenzo*, 1990 U.S. Dist. LEXIS 7362, at 3 ("By denying as stated requests 5 and 6, and then admitting a more narrow interpretation of the request, the defendants proffer an ambiguous response that does not 'fairly meet the substance of the request.'"); *Deya*, 2011 U.S. Dist. LEXIS 44337, at 8 ("Rule 36(a)(4) itself permits a qualified response, if necessary. But it does not authorize a respondent to evade the request for admission with an answer to some imaginary, collateral question."); *Kelatron v. Marlyn Nutraceuticals*, 2013 U.S. Dist. LEXIS 119590, at 9-12 (D. Utah Aug. 21, 2013) (holding that denials that include facts unrelated to the substance of the requests do not fairly respond to the substance of the requests). Accordingly, the responses to the aforementioned requests should be deemed insufficient.

#### **B. Defendants' responses made "subject to" objections is improper**

The responses to requests to admit nos. 8, 10, 11, 15, 17, 18, 22, 24, 25, 118, 119, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 201, 202, 203, 204, 205, 206, 207, 208, 209, 211, 212, 213, 214, 215 and 216 are deficient because the responses lodge objections but then purport to respond "subject to" the objections. Rule 36 is clear that a party may answer or object, but not both. *See Fed. R. Civ. P. 36(a)* ("the party to whom the request is directed serves upon the party requesting the admission a written answer or objection addressed to the matter ....") (emphasis added); *Kutner Buick, Inc. v. Crum & Foster Corp.*, 1995 U.S. Dist. LEXIS 12524, at 10-11

(E.D. Pa. Aug. 24, 1995) ("Defendant cannot have it both ways. Rule 36(a) provides that a matter is admitted unless the responding party denies the matter *or* objects to it. If an objection is made, the rule requires that the responding party shall set forth the reasons for the objection. The rule does not state that a party may also deny the request in case the reviewing court does not accept its reasons for objecting.") (emphasis in original). Accordingly, the aforementioned objections should be overruled.

### **C. Defendants' objections to terminology lack merit**

The responses to requests to admit nos. 8, 15, 22, 178, 190, 191, 192, 193, 194, 195, 196, 197 and 198 fail to comply with applicable law. Here, Defendants object to various phrases used in the requests as vague and ambiguous even though the context in which the phrases are used is clear and the meaning is well known to Defendants. As courts have repeatedly held, in responding to requests for admissions parties should exercise reason and common sense to attribute an ordinary definition to the phrase used. *See Deakins v. T.S. Pack*, 2012 U.S. Dist. LEXIS 9409, at 88 (S.D. W. Va. Jan. 25, 2012).

### **D. Defendants' responses are vague and ambiguous**

The responses to requests to admit nos. 46, 47, 48, 49, 50, 51, 52, 53 and 154 are vague and ambiguous. For instance, Request no. 46 provides:

**REQUEST NO. 46:** Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Ulmsten or any of his studies, the fact that Professor Ulmsten was your paid consultant.

#### **RESPONSE:**

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 46. Defendants admit that, at present, they have not identified any TVT marketing materials that expressly state that Professor Ulmsten was a paid consultant.



Rule 36 requires that “[t]he answering party may assert lack of knowledge or information as a reason for failing to admit or deny only if the party states that it has made reasonable inquiry and that the information it knows or can readily obtain is insufficient to enable it to admit or deny.” Fed. R. Civ. P. 36(4). Here, after asserting lack of knowledge and an inability to admit or deny, Defendants go on to admit the request. This type of answer makes no sense and should be deemed insufficient. *See Havenfield*, 67 F.R.D. at 97 (answers that appear to be evasive and ambiguous are impermissible). The Defendants’ post-objection admissions should stand.

Dated: January 9, 2014

Respectfully submitted,

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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

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**CIVIL ACTION NO. 2:12-md-02327**  
**MDL No. 2327**  
Judge Joseph R. Goodwin

**CERTIFICATE OF SERVICE**

I hereby certify that I filed the foregoing document on January 9, 2014, using the Court's CM-ECF filing system, thereby sending of the filing to all counsel of record for this matter.

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